

PATENT Docket No.: 1038-844

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Loosmore, et al. )  
Application No.: 09/210,995 )  
Filing Date : December 15, 1998 )  
Title : Multi-Component Vaccine Comprising At Least )  
Two Antigens From Haemophilus influenzae )  
To Protect Against Disease )  
Grp/AU : 1645 )  
Examiner : Jana A. Hines )

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**APPEAL BRIEF AND REQUEST FOR**  
**EXTENSION OF TIME** EC:1402  
**TOTAL PAGES 78**

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**BY FACSIMILE** 703-872-9307

The Commissioner of Patents and Trademarks  
BOX AF,  
Washington, D.C.  
20231, U.S.A.

Dear Sir:

**Introduction**

This Appeal Brief is submitted pursuant to applicant's appeal from a Final Rejection of claims 6-24 dated October 22, 2002. A Notice of Appeal was filed on April 22, 2003. The enclosed Credit Card Payment Form includes the prescribed fee. In the event of underpayment or overpayment please apply any additional charges or refunds to USPTO Deposit Account Number 500715. Three copies of the Appeal Brief are provided herewith.

**Extension of Time**

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of four months of the period for filing this Appeal Brief. The enclosed Credit Card Payment Form includes the prescribed fee. In the event of underpayment or overpayment please apply any additional charges or refunds to USPTO Deposit Account Number 500715.

It is submitted that these findings are a surprising result. In addition, it is further surprising that H1N1 would enhance the vigorous antibody response to H91A H1N1, since it is a weaker immunogen.

Furthermore, these results are unexpected in the field of combination vaccines.

There is little expectation of success that simply mixing existing vaccine antigens will not result in incompatibilities amongst the various antigens, resulting in loss of stability or reduced potency. Indeed a synergistic effect increasing potency. Immune interference cannot be predicted.

Others skilled in the art of combination vaccines have found that the preparation of combination vaccines is far from straight forward. For example Caulfield et al (2001) report on the need for a balanced formulations of vaccine components in the preparation of DTP combination vaccines to circumvent interference with the components. Van den Bosch et al (2003) have also reported that the addition of a potential antigen (Pal A) from A. pleuropneumoniae can completely

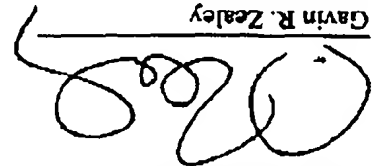
eliminate the positive efficacy of known antigens (ApxI and II) when combined (see abstract). For all these reasons, it is submitted that claims 6 to 24 are patentable over the applied art and the rejection thereof under 35 USC 103(a) as being unpatentable over Barenkamp

in view of Loomore et al.

#### (II) Summary

Having regard to the above detailed discussion, it is submitted that the Examiner is in error in rejecting claim 6 to 24 as being unpatentable and hence the rejection thereof under 35 USC 103(a) as being unpatentable over the combination of Barenkamp (WO 97/36914) in view of Loomore et al, should be REVERSED.

Respectfully submitted,



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